

K083147

GE Healthcare

GE Discovery MR450

510(k) Premarket Notification

NOV - 4 2008

Section 5 - 510(k) Summary

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510(k) Summary

This 510(k) summary of safety and effectiveness information is submitted in accordance with the requirements of 21 CFR Part 807.92(c).

Submitter: GE Healthcare
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Date Prepared: October 20, 2008

Device Name:

Proprietary Name: Discovery MR450

Classification Name: Magnetic Resonance Diagnostic System, 21 CFR 892.1000, 90-LNH

Predicate Devices:

GE 1.5T Signa® HDx Magnetic Resonance System (K052293)

GE Signa® MR750 System (K081028)

Device Description:

The GE Discovery MR450 is a new MR system that is substantially equivalent to previously cleared 1.5T /3.0T MR systems. All utilize superconducting magnets, gradients, and radio frequency coils and electronics to acquire data in single voxel, two dimensional, or three dimensional datasets. The 1.5T GE Discovery MR450 features a superconducting magnet operating at 1.5 Tesla. The data acquisition system accommodates up to 32 independent receive channels in various increments, and multiple independent coil elements per channel during a single acquisition series. The system uses a combination of time-varying magnetic fields (gradients) and RF transmissions to obtain information regarding the density and position of elements exhibiting magnetic resonance. The system can image in the sagittal, coronal, axial, oblique and double oblique planes, using various pulse sequences and reconstruction algorithms.. The 1.5T GE Discovery MR450 is designed to conform to NEMA DICOM standards (Digital Imaging and Communications in Medicine).

Indications for Use:

The Discovery MR450 is a whole body magnetic resonance scanner designed to support high resolution, high signal-to-noise ratio, and short scan times. It is indicated for use as a diagnostic imaging device to produce axial, sagittal, coronal, and oblique images, spectroscopic images, parametric maps, and/or spectra, dynamic images of the structures and/or functions of the entire body, including, but not limited to, head, neck, TMJ, spine, breast, heart, abdomen, pelvis, joints, prostate, blood vessels, and musculoskeletal regions of the body. Depending on the region of interest being imaged, contrast agents may be used.

The images produced by the Discovery MR450 reflect the spatial distribution or molecular environment of nuclei exhibiting magnetic resonance. These images and/or spectra when interpreted by a trained physician yield information that may assist in diagnosis.

Comparison with Predicate Devices:

The indications for use for the Discovery MR450 are similar to those for the GE Signa® HDx Magnetic Resonance System and the GE Signa® MR750.

Comparison statement between Discovery MR450 and 1.5T Signa® HDx system :

The GE Discovery MR450 is a new device design that is similar to the previously cleared 1.5T HDx MR system (K052293) with the main differences being new receive chain architecture that will support up to 32 channels in various channel increments, an increase in the amplitude and slew rate of the gradient output, water-cooling of the radio frequency amplifiers, an increased patient table weight limit, faster image reconstruction, and new system packaging. The new receive chain architecture supports up to 32 independent receive channels and will accommodate expansion to 128 channels through future product development. The amplitude and slew rate of the gradient output has been increased relative to the predicate Signa® HDx system. The patient table has been designed to support up to five hundred pounds. Electrical components have been updated to minimize obsolescence issues. Also, the system packaging has incorporated water cooling and has been designed to support the new receive channel architecture, improved gradients, and future expandability to 128 channels.

Comparison statement between Discovery MR450 and GE Signa® MR750:

The GE Discovery MR450 is also similar to the previously cleared Signa® MR750 3T system (K081028). The primary difference is the strength of the static magnetic field and adjustments to the corresponding frequency specific components. The software and user interface, RF receive chain, patient handling, gradient performance and aesthetic specifications are common with the Signa® MR750. The RF transmit coil has been altered to be compatible with the same gradient coil as the Signa® MR750, and the transmit RF amplifier is similar to the 1.5T HDx product. There are applications improvements that

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resulted from developmental work done to the feature set included with the MR450, but these are significantly equivalent to the Signa® MR750.

Summary of Studies:

As stated in the FDA document "Guidance for the Submission of Premarket Notifications for Magnetic Resonance Diagnostic Devices" the following parameters have been measured and documented through testing to NEMA, IEC or ISO standards (as referenced throughout this submission and listed in Section 9):

Performance:

- Signal-to-noise ratio (SNR)
- Geometric distortion
- Image uniformity
- Slice thickness
- Spatial resolution

Safety

- Static field strength
- Acoustic noise
- dB/dt
- RF heating (SAR)
- Biocompatibility

The Discovery MR450 has been designed to comply with applicable IEC standards. It shall be certified by a Nationally Recognized Testing Laboratory to conform to IEC, UL and CSA standards prior to commercialization of the system.

Conclusion:

It is the opinion of GE that the GE Discovery MR450 is substantially equivalent to the 1.5T Signa® HDx MR System and GE Signa® MR750.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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GE Medical Systems LLC
% Mr. Jay Y. Kogoma
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2307 E. Aurora Rd., Unit B7
TWINSBURG OH 44087

NOV - 4 2008

Re: K083147

Trade/Device Name: Discovery MR450
Regulation Number: 21 CFR 892.1000
Regulation Name: Magnetic resonance diagnostic device
Regulatory Class: II
Product Code: LNH
Dated: October 23, 2008
Received: October 24, 2008

Dear Mr. Kogoma:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

21 CFR 876.xxx	(Gastroenterology/Renal/Urology)	240-276-0115
21 CFR 884.xxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 894.xxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometrics' (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,



Joyce M. Whang, Ph.D.
Acting Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K083147

Device Name: Discovery MR450

Indications for Use:

The Discovery MR450 is a whole body magnetic resonance scanner designed to support high resolution, high signal-to-noise ratio, and short scan times. It is indicated for use as a diagnostic imaging device to produce axial, sagittal, coronal, and oblique images, spectroscopic images, parametric maps, and/or spectra, dynamic images of the structures and/or functions of the entire body, including, but not limited to, head, neck, TMJ, spine, breast, heart, abdomen, pelvis, joints, prostate, blood vessels, and musculoskeletal regions of the body. Depending on the region of interest being imaged, contrast agents may be used.

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Prescription Use X AND/OR Over-the-Counter Use _____
(21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

John H. Wang
(Division Sign-Off)
Division of Reproductive, Abdominal and
Radiological Devices
510(k) Number K083147